HL7 RCRIM WG

FHIR AdverseEvent Resource

CALL MINUTES: Friday, March 24, 2017

Meet online at www.webex.com, meeting number: 196 412 889
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Project Wiki

http://wiki.hl7.org/index.php?title=FHIR_Adverse_Event_Resource

References

1) Search the FDA Acronyms & Abbreviations Database: http://www.fda.gov/AboutFDA/FDAAcronymsAbbreviations/default.htm

2) FHIR Conformance Rules: http://hl7.org/fhir/conformance-rules.html
   a) See 1.12.2 Cardinality

Agenda

1. Review minutes from March 10
2. Review of action items
   a. Vocab group re use of MedDRA
   b. Consider how to represent reaction vs. resulting condition
   c. For type – propose value set bindings (e.g. MedDRA)
   d. For category – make mandatory and add a warning flag
   e. For seriousness – change to serious and determine how to add category or criteria if true
   f. For causality determine what current E2B and MedWatch require – determine if assessment and method are redundant.
3. Other issues
   a. Tracking issues in G-FORGE and Zulip
4. Agenda items for Friday, April 7, at 10 AM ET.

Minutes

1. Minutes Approval: Move (deferred)
2. The adverse event resource has been proposed as a candidate for the Clinicians on FHIR connectathon at the Madrid WG meeting. For those interested David Hay has built the following tool for experimenting with building profiles. The tool is open and can be found here for experimentation: http://clinfhir.com
3. Discussed need to add further granularity to description of the event – e.g. what happened and then what was the result of what happened. So for example someone fell off a ladder and as a result broke their leg.
   i. Therefore will add two new data types
   ii. ADD AdverseEvent.event – codeable concept with SNOMED CT
   iii. ADD AdverseEvent.resultingCondition – this will be a reference to Condition
   iv. REMOVE "reaction" as this is a subset of a type of resulting Condition
4. Discussed the level of granularity between category and type. Decided one additional intermediary level was needed.
   i. CHANGE name of category to AdverseEvent.kind – retain adverse event|potential adverse event as fixed with a flag
   ii. Category can then be expanded to include a discrete list of broad event classifications
      1. Adverse Event
      2. Serious Adverse Event
      3. Product Problem
      4. Product Use Error
      5. Medical Device Use Error
      6. Problem with Different Manufacturer of Same Medicine
      7. Near Miss
      8. Unsafe Condition
   iii. Event type - use MedDRA codes such as "Fever" 10016558. Note that MedDRA codes are maintained for adverse event reporting through the National Library of Medicine UMLS and can be accessed for with a no-cost UMLS license. Note that MedDRA also has coded data elements for describing product issues, and under the Social Circumstances SOC, event types such as environmental problems that can be used to describe patient safety issue.
5. The group discussed changes to the causality data type.

i. CHANGE AdverseEvent.suspectEntity.causality to a codeable concept
ii. ADD to AdverseEvent.suspectEntity.causality the terms defined in the WHO Uppsala Causality Assessment System: https://www.who-umc.org/media/2768/standardised-case-causality-assessment.pdf
    1. Terms are (with definitions)
        a. Certain
        b. Probably/Likely
        c. Possible
        d. Unlikely
        e. Conditional/Unclassified
        f. Unassessable/Unclassifiable
iii. REMOVE Causality Assessment
iv. REMOVE Causality Result
v. Causality Method – add various methodologies as per literature.

3) ACTION ITEMS
   a) Elaine will develop a list of changes from the last three meetings and send a spreadsheet to Rik.
   b) Rik will apply changes to the draft build for review.

Agenda for April 7, 2017:

5. Review minutes from March 24
6. Review of action items
7. Other issues
    a. Tracking issues in G-FORGE and Zulip
8. Agenda items for Friday, April 21, at 10 AM ET.

Additional notes:

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM275638.pdf
Guidance on classification of events.

Categories

Adverse Event
Product Problem
Product Use Error
Problem with Different Manufacturer of Same Medicine
Serious Adverse Event

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or Permanent Damage
- Congenital Anomaly or Birth Defect
- Required medical or surgical intervention to prevent permanent impairment or damage (Devices)
- Other Serious (important medical events).

Product Problem

- Suspected counterfeit product

- Suspected contamination
- Questionable stability
- Physical defects (such as color, powdering, chipped)
- Defective components for both devices or drug products (such as a patch that is hard to peel othe backing off)
- Product confusion (caused by name, labeling, design or packaging)
- Suspected super potent or sub potent medication
- Labeling problems caused by printing errors/omissions
- Failure to meet performance specification (including labeling claims) or failure to perform as intended – medical devices.

Product Use Error

Medical device Use Error

Problem with Different Manufacturer of Same Medicine

Outcome Attributed to Adverse Event (Incident)

- Death
- Life-threatening
- Hospitalization
- Disability or Permanent Damage
- Congenital Anomaly or Birth Defect
- Required medical or surgical intervention to prevent permanent impairment or damage (Devices)
- Other Serious (important medical events).

Event types:
Adverse Event
Serious Adverse Event
Unexpected Adverse Event
Protocol Deviation
Non adverse event – non medical events that involve social, psychological or economic harm rather than physical harm

Potential Adverse Event

Near Miss
Unsafe Condition (is this an event or a potential adverse event or both??)

Suspect Product
- Prescription of over the counter medication
- Biologic product such as blood components, blood derivatives, allergenics, human cells and tissues used for transplantation (e.g. tendons, ligaments and bone) and gene therapy
- Nutrition product, such as a vitamin or mineral, herbal remedy, infant formula or medical food or beverage
- Cosmetic product
- Foods including beverages (especially serious food allergens)

Note: Event abated after use stopped or dose reduced? Event reappeared after reintroduction?